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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/310,844	05/12/1999	DAVID J. ECKER	IBIS-0171	9454

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EXAMINER

SCHMIDT, MARY M

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/310,844

Applicant(s)

ECKER ET AL.

Examiner

Mary Schmidt

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 87-100,108 and 110-113 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 87-100,108 and 110-113 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Please note that the Examiner of record has changed in the instant Application. Please see the concluding remarks below for information on how to reach the Examiner.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

3. The specification stands objected to for the embedded references to computer web sites. Applicant responded to the previous objection on page 46 that "Applicants have amended the specification... to delete hyperlinks and other forms of browser-executable code." However, the amendments provided in the response delete the "http://www" before the remainder of the address, but add back the remainder of the web cites by amendment. Applicant therefore has not complied with the rules. The specification must be completely void of web cite references.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 87-100, 108 and 110-113 are provisionally rejected under the judicially created

doctrine of obviousness-type double patenting as being unpatentable over claims 11, 13, 14 and 16 of copending Application No. 09/310,735. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 87-100, 108 and 110-113 are drawn to compositions having a specific type of secondary structure found for instance in the specific nucleic acid sequences claimed (ie. SEQ ID NO:23 for instance) which would be considered one of the compositions claimed in Application 09/310,735. Application 09/310,735 claims compositions identified from a method of identifying at least one molecular interaction site on said target RNA generating in silico a virtual library of compounds predicted or calculated to interact with said molecular interaction site; and comparing three dimensional representations of said target RNA with members of the virtual library of compounds to generate a hierarchy of said compounds ranked in accordance with their respective ability to form physical interactions with said molecular interaction site. A sequence search of instant SEQ ID NO:23 identified that this sequence was disclosed in Application 09/310,735 as a composition which may be identified by the methods claimed in '735. Therefore, the instantly claimed compositions are considered to read on claims 11 and 14 of '735 drawn to compounds identified as having the ability to modulate activity of a target RNA as well as the compositions of claims 13 and 14 of '735 since the limitations "pharmaceutical, agricultural chemical or industrial chemical" are not considered to breath further life and meaning into the compositions of the instant claims having the sequences such as those claimed in the instant Application as SEQ ID NOS: 23-25, which have the claimed secondary structure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. Claims 87-100, 108, 110, 112 and 113 are rejected under 35 U.S.C. 102(b) as being anticipated by McKnight et al., Immunogenetics 30, 145-147 (1989) for the same reasons of record as set forth in the Official Action mailed 10/30/01.

Applicant's arguments filed 02/07/02 have been fully considered but they are not persuasive.

In the Official Action mailed 10/30/01, the previous Examiner explained that since McKnight et al. taught the rat interleukin-2 gene encoding RNA comprising the sequence of instant SEQ ID NO:23 and 25, the sequence taught by McKnight et al. must have the same secondary structure instantly claimed.

Applicant argues that it has not been established that the McKnight reference contains the secondary structure recited in claim 87. In response, Applicant is referred to MPEP 2112.01 which teaches that "where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established...." "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." "McKnight et al. taught compositions having a sequence which is the same as instant SEQ ID NO:23, thus having the same secondary structure as that instantly claimed.

Applicant further argues the McKnight reference does not anticipate every element of the claim, specifically the limitation "not more than seventy nucleotides." In response, claim 87 is broadly drawn to any RNA comprising a joined sequence of at least twenty-nine but not more than seventy nucleotides...." In view of the open "comprising" language, the claim reads on

sequences which are longer than 70 nucleotides and thus reads on the sequence taught by McNight et al. Applicant further notes that claims 110, 112 and 113 recite an "RNA fragment" and argues that McNight et al. does not teach a "fragment" comprising the claimed sequences. Again, however, since the composition taught by McNight was known in the art to comprise the claimed composition, and in view of the "open" comprising language, the limitation "fragment" is not considered to breath further life and meaning into what was already a known composition in the art. Since Applicant does not specifically claim a fragment of a specific size, without claiming any sequence which "comprises" the claimed sequence, the prior art stands.

7. Claims 87-100, 108, 110, and 111 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. PNAS, vol. 82, pp. 7284-7288 (November 1995) for the same reasons of record as set forth in the Official Action mailed 10/30/01.

Applicant's arguments filed 02/07/02 have been fully considered but they are not persuasive.

In the Official Action mailed 10/30/01, the previous Examiner explained that since Chen et al. taught the gibbon and human interleukin-2 gene encoding RNA comprising the sequence of instant SEQ ID NO:24, the sequence taught by Chen et al. must have the same secondary sequence structure instantly claimed.

Applicant argues that it has not been established that the Chen reference contains the secondary structure recited in claim 87. In response, Applicant is referred to MPEP 2112.01 which teaches that "where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established...."When

the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.”“ Chen et al. taught compositions having a sequence which is the same as SEQ ID NO:24, thus having the same secondary structure as that instantly claimed.

Applicant further argues the Chen reference does not anticipate every element of the claim, specifically the limitation “not more than seventy nucleotides.” In response, claim 87 is broadly drawn to any RNA comprising a joined sequence of at least twenty-nine but not more than seventy nucleotides....” In view of the open “comprising” language, the claim reads on sequences which are longer than 70 nucleotides and thus reads on the sequence taught by Chen et al. Applicant further notes that claims 110, 112 and 113 recite an “RNA fragment” and argues that Chen et al. does not teach a “fragment” comprising the claimed sequences. Again, however, since the composition taught by Chen was known in the art to comprise the claimed composition, and in view of the “open” comprising language, the limitation “fragment” is not considered to breath further life and meaning into what was already a known composition in the art. Since Applicant does not specifically claim a fragment of a specific size, without claiming any sequence which “comprises” the claimed sequence, the prior art stands.

8. Claims 87-91, 94-98, 108, 110, 112 and 113 are rejected under 35 U.S.C. 102(e) as being anticipated by Fu et al., U.S. Patent No. 6,090,620) for the same reasons of record as set forth in the Official Action mailed 10/30/01.

Applicant's arguments filed 02/07/02 have been fully considered but they are not persuasive.

In the Official Action mailed 10/30/01, the previous Examiner explained that since Fu et

al. taught the WRN gene encoding RNA comprising the sequence of instant SEQ ID NO:22 and 25, the sequence taught by Chen et al. must have the same secondary sequence structure instantly claimed.

Applicant argues that it has not been established that the Fu reference contains the secondary structure recited in claim 87. In response, Applicant is referred to MPEP 2112.01 which teaches that “where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established....” When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” “Fu et al. taught compositions having a sequence that is the same as SEQ ID NO:23, thus having the same secondary structure as that instantly claimed.

Applicant further argues the Fu reference does not anticipate every element of the claim, specifically the limitation “not more than seventy nucleotides.” In response, claim 87 is broadly drawn to any RNA comprising a joined sequence of at least twenty-nine but not more than seventy nucleotides....” In view of the open “comprising” language, the claim reads on sequences which are longer than 70 nucleotides and thus reads on the sequence taught by Fu et al. Applicant further notes that claims 110, 112 and 113 recite an “RNA fragment” and argues that Fu et al. does not teach a “fragment” comprising the claimed sequences. Again, however, since the composition taught by Fu was known in the art to comprise the claimed composition, and in view of the “open” comprising language, the limitation “fragment” is not considered to breath further life and meaning into what was already a known composition in the art. Since Applicant does not specifically claim a fragment of a specific size, without claiming any

sequence which "comprises" the claimed sequence, the prior art stands.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.



JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

M. M. Schmidt
May 6, 2002